

B2  
Claim 18, line 1, after "composition", insert --  
effective for reducing growth hormone serum levels--.

Claim 20, line 5, delete "Claim 1", insert --Claim  
22--.

In the Specification:

Cancel from page 3, line 27 from "In addition...",  
thru line 36 ....hormones".

REMARKS

Applicants undersigned attorney thanks the Examiner for the courtesy of a personal interview on July 8, 1986, in which the Examiner indicated that he would allow Claims 22 and 23 upon submission of test data showing superiority of the presently claimed compounds over the cited art compounds, in particular, the Bauer compounds. The provision of absolutely comparative in vivo test data is time-consuming and exceedingly expensive. Nevertheless, data is currently available, both in Applicants laboratory and from the published data of Bauer which, in Applicants view, shows the superiority of Applicants compounds.

While not conceding the original scope of claiming to be too broad, Applicants have submitted herewith a generic claim of substantially narrower scope than amended Claim 1 and furthermore, have made certain presently claimed compounds dependent on said narrower generic claim. In accordance with the requirements of the Rule asnd to reduce issues, Claims 1, 6 and 8 have been cancelled without prejudice so that there shall be no greater number of claims in the case than were finally rejected.

Notwithstanding the submission of declaration data which shall be discussed hereinbelow, Applicants again respectfully traverse the rejection of the claims over Sarantakis in view of Bauer. Applicants respectfully draw the Examiner's attention to a paper by Bauer in Life Sciences, which presents the actual test data which apparently Bauer utilizes in his patent. A copy of this paper is enclosed herewith.

Sarantakis teaches that the terminal amino acid should be in the amino alcohol form. The Bauer patent does not appear to indicate a preference for the terminal amide or the terminal alcohol form. However, in the Bauer paper at page 1136, first paragraph, there is a clear teaching that the amino alcohol form improves the in vivo activity relative to the the acid amide form. If the Examiner's line of argument is followed that Bauer

teaches that it would be desirable, in order to enhance growth hormone reduction capability, that the peptides of Sarantakis be shortened, the corollary must be accepted that the terminal amino alcohol form is to be preferred. That of course, is contrary to Applicants finding that the combination of a valine vicinal to the cysteine with terminal amino acid amide group is certainly not suggested by the combination of the Bauer patent and the Sarantakis patent, when read in the light of Bauer's publication. Hence, it is respectfully submitted that Claim 1 and the claims dependent thereon are not precluded from patentability under 35 U.S.C. 103.

Applicants respectfully take issue with the Examiner's indication that the specification is objectionable under 35 U.S.C. 132, as introducing new matter in the change on page 3, line 29.

Applicants respectfully submit that such a position is an excessively narrow reading of the law. It is Applicants position that the purpose of 35 U.S.C. 132 is to prevent an applicant, during prosecution of his application from inserting a potential basis for claiming which was not present in the application as filed. It is well recognized that an applicant may, if he wishes, restrict the scope of his claims from that originally requested during the course of prosecution. If the Examiner objects to terminology in the specification as filed as being unsupported in fact, applicant sees no reason why he should not be permitted to, similarly, restrict the scope of the specification in order to bring it more closely in line with facts which can be proved. As stated previously, a specification has many purposes and one of said purposes is to inform the reader thereof of the utility or the possible utility of the invention. At this point, Applicants do not claim cancer utility. Nevertheless, it is known in the art that some of the properties of Applicants compounds have, upon occasion, been known to have influence upon the course of growth of neoplastic tumors. Hence, it is submitted that Applicants position is entirely proper and no way misleading.

Finally, Applicants respectfully submit that in demanding entire cancellation of certain sections of the specification, the Examiner is being inconsistent in his reading of the words "new matter". If restriction of a recitation from positive to tentative is considered to be new matter, it would clearly be new matter to go yet further and cancel a portion of the specification entirely. Needless to say, it is well recognized in patent practice that the entire cancellation of such a set

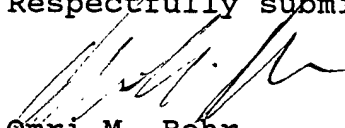
of statements is not new matter and hence, it is respectfully submitted that restricting the scope of the statement in the manner requested by Applicants is entirely proper, is not a violation of 35 U.S.C. 132, and should be permitted to remain. However to expedite resolution of the issues, this subject matter has been cancelled.

In the accompanying Declaration, in vivo test data is compared for two of the compounds (RC121 and RC160) claimed in the present application with best Bauer compound reported in the Bauer paper. It is not desired to burden the record by being repetitive, however, a review of the declaration will show that Applicants compounds are superior to the Bauer compounds not only in terms of absolute superiority in GH suppression, but also in terms of effective life in the physiological system. It is further shown that with respect to gastric acid suppression, Applicants compounds are also superior to the best Bauer compound.

As stated above, all of Applicants compounds as presently claimed have a terminal amino acid amide group. Sarantakis and the Bauer paper clearly teach the desirability of an amino alcohol terminal group as being preferred, even though some activity is noted for the amino acid amide groups. Further, while Sarantakis mentions valine as a possible group vicinal to the cysteine of the core hexapeptide moiety, this grouping is nowhere suggested by Bauer in his shotgun disclosure of groups that may constitute the peptides which he considers.

It is respectfully submitted that the foregoing arguments, per se, and taken in combination with the accompanying Declaration, are sufficient to overcome the Examiner's initial view of the Sarantakis and Bauer patents. In view thereof, it is respectfully requested that the claims as amended be allowed and passed to issue forthwith.

Respectfully submitted,

  
Omri M. Behr  
Regis. No. 22,940

gen.15  
docu.31